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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|------------------------------------|-----------------------|--------------------------|-------------------|--|
| 09/812,945 | 03/27/2001 | Hsuan-Yin Lan-Hargest | 12938-002001 | 12938-002001 5280 | |
| 27890 75 | 590 03/30/2006 | | EXAMINER | | |
| STEPTOE & JOHNSON LLP | | | WANG, SHENGJUN | | |
| 1330 CONNEC WASHINGTO | CTICUT AVENUE, N.W. N. DC 20036 | | ART UNIT | PAPER NUMBER | |
| ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | ., 20 5000 | | 1617 | | |
| | | , | DATE MAIL ED: 03/30/2006 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | | Application No. | Applicant(s) | | | | |
|--|--|--|---|--------------|--|--|--|
| | | 09/812,945 | LAN-HARGEST ET AL. | | | | |
| | | Examiner | Art Unit | | | | |
| | | Shengjun Wang | 1617 | | | | |
| Period fo | The MAILING DATE of this communication app or Reply | ears on the cover sheet with the | correspondence a | ddress | | | |
| WHIC - External after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE in an analysis of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. In period for reply is specified above, the maximum statutory period vere to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATIO 36(a). In no event, however, may a reply be ti vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONI | N. mely filed n the mailing date of this ED (35 U.S.C. § 133). | • | | | |
| Status | | | | | | | |
| 1) 🛛 | Responsive to communication(s) filed on 10 Ja | nnuary 2006. | | | | | |
| 2a)□ | | action is non-final. | | | | | |
| 3)□ | | | | | | | |
| , | closed in accordance with the practice under E | | | | | | |
| Dispositi | on of Claims | • | | | | | |
| 4) 又 | Claim(s) <u>1-7,10-15,17,18,21-24,33-44,46-53 ar</u> | nd 67-85 is/are pending in the ar | oplication. | | | | |
| | 4a) Of the above claim(s) <u>13-15,21-24,33-39,4</u> | · · · | • | ation. | | | |
| | Claim(s) is/are allowed. | | | | | | |
| · | ☑ Claim(s) <u>1-7,10-12,17,18,40,42-44,46 and 83</u> is/are rejected. | | | | | | |
| | | | | | | | |
| | Claim(s) are subject to restriction and/or | | | | | | |
| Applicati | on Papers | | | | | | |
| | The specification is objected to by the Examine | • | | | | | |
| · | The drawing(s) filed on is/are: a) ☐ acce | | Evaminer | | | | |
| .0/ | Applicant may not request that any objection to the | | | | | | |
| | Replacement drawing sheet(s) including the correct | · · | | CFR 1 121(d) | | | |
| 11) | The oath or declaration is objected to by the Ex | | | | | | |
| | inder 35 U.S.C. § 119 | | | | | | |
| | Acknowledgment is made of a claim for foreign | priority under 35 H S C & 110/a | 1) (d) or (f) | | | | |
| | ☐ All b)☐ Some * c)☐ None of: | priority under 55 0.5.6. § 119(a | i)-(u) or (r). | | | | |
| ٠,١ | 1. ☐ Certified copies of the priority documents | s have been received | | | | | |
| | 2. Certified copies of the priority documents | | ion No | | | | |
| | 3. Copies of the certified copies of the prior | | | l Stage | | | |
| | application from the International Bureau | | ca iii tiilo i vationa | Clago | | | |
| * 5 | see the attached detailed Office action for a list | ` '' | ed. | | | | |
| _ | | | - | | | | |
| Attachmen | t(s) | | | | | | |
| | e of References Cited (PTO-892) | 4) Interview Summary | | | | | |
| | e of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail D | | ·O 152) | | | |
| | nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date | 5) Notice of Informal F 6) Other: | -atent Application (PT | 0-102) | | | |

Receipt of applicants' amendments and remarks submitted January 10, 2006 is acknowledged.

Note the elected invention is invention group IVa, A method of inhibiting histone deacetylation activity in cells comprising contacting the cells with an effective amount of a compound of formula (I), thereby treating cancer, wherein X1, X2 together with the carbon attached is a hydroxamic acid group, and wherein A is a phenyl group.

This application contains claims 1-7, 10-15, 17-18, 21-24,33-44, 46-53, 67-75 read on to an invention nonelected with traverse in Paper filed April 11, 2005 and October 11, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims Objections

- 1. Claims 41, 76-82, 84-85 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 2. Claims 40 and 76-85 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 defined as the aryl groups may

substituted with alkylalkenyl, alkynyl, alkoxy. The further limitation with dimethylamino, and chloro substituents is not further limiting the claims.

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Claim Rejections 35 U.S.C. 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 4. Claims 1-2, 4-7, 9-10, 12, 17-18, 40, 42, 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Parsons et al (WO 98/55449).
- 5. Parsons teaches a method of inhibiting cancer cell growth by contacting the cell with a histone deacetylation inhibiting hydroxamic acids, wherein the hydroxamic acids have an polar group linked to the hydroxamic acid moiety through a linker, wherein the polar group may be amino (CNH2, CNR), hydroxyalkyl, haloalkyl, and wherein the polar groug may have aryl substituents. The linker may contain unsaturated carbon-carbon bond. See, particularly, the abstract, pages 6-16, and particularly, compound Vd in claim 15. Note the claims as currently pending read as "said hydrocarbone chain being optionally substituted with ... amino, nitro, cyan,..." and further being optionally interrupted by -)-, N(Re)--N(Re)-C(O)-O-, O-C(O)-N(Re)-, ..." Therefore, the claims read on the compounds defined by Parsons et al., e.g., an compounds with formula of Ary-CHNH2-linker-C(O)NH-OH (substituted), or Ary-NR-linker-

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C(O)NH-OH (interrupted). Further, compounds recited in claims 83 would read on the compound disclosed by Parsons et al., i.e., X1 is dimethylamino.

Claim Rejections 35 U.S.C. 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 1-2, 4-7, 9-10, 12, 17-18, 40, 42, 44-46, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parsons et al (WO 98/55449).
- 8. Parsons teaches a method of inhibiting cancer cell growth by contacting the cell with a histone deacetylation inhibiting hydroxamic acids, wherein the hydroxamic acids have an polar group linked to the hydroxamic acid moiety through a linker, wherein the polar group may be amino, hydroxyalkyl, haloalkyl. The linker may contain unsaturated carbon-carbon bond. See, particularly, the abstract, pages 6-16, and particularly, compounds Vg and Vd in claim 15. Note the claims as currently pending read as "said hydrocarbon chain being optionally substituted with ... amino, nitro, cyano,..." and further being optionally interrupted by -)-, N(Re)- -N(Re)-C(O)-O-, O-C(O)-N(Re)-, ..." Therefore, the claims read on the compounds defined by Parsons et al., e.g., an compounds with formula of Ary-CHNH2-linker-C(O)NH-OH (substituted), or Ary-NR-linker-C(O)NH-OH (interrupted). Further, compounds recited in claims 82 would read on the compound disclosed by Parsons et al., i.e., X1 is dimethylamino, claim 83 is obvious because of the polar substituent, Chloro group.

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9. Parsons et al do not teach expressly the employment of the particular compounds herein for treating cancer.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the compounds herein for treating cancer because those compounds are disclosed as useful for treating cancer. The employment of the particular compounds herein is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

Allowable subject matter

Claim 1 would be allowable if being limited to the elected invention, i.e., A method of inhibiting histone deacetylation activity in cells comprising contacting the cells with an effective amount of a compound of formula (I), thereby treating a disorder mediated by histone deacetylase, wherein the disorder is a cancer, and the compound are defined therein, and wherein X1, X2 together with the carbon attached is a hydroxamic acid group, and wherein A is a phenyl group.

and L being without the options.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKENGUNWARE PRIMARY EXAMINER Shengjun Wang Primary Examiner Art Unit 1617

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